K003724

DEC 21 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
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Marie Holm, Associate Product Regulations Manager, Regulatory/Clinical Affairs

DEVICE NAME

CBMYOtherm™ XP Cardioplegia Delivery System with Carmeda® BioActive Surface

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

MYOtherm™ XP Cardioplegia Delivery System (K971105)
CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface (K973475)

DESCRIPTION OF DEVICE

The CBMYOtherm™ XP Cardioplegia System with Carmeda ® BioActive Surface is designed to mix arterial blood from oxygenators with asanguineous cardioplegia solution. The blood/cardioplegia solution is then cooled/warmed and delivered to the patient.

The CBMYOtherm™ XP Cardioplegia System with Carmeda® BioActive Surface is coated with a non-leaching bioactive heparin surface, which provides thromboresistant blood contact surfaces.

STATEMENT OF INTENDED USE

The CBMYOtherm™ XP Cardioplegia System with Carmeda ® BioActive Surface is a device intended for the mixing, warming/cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio.

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The MYOtherm™ XP Cardioplegia Delivery System is designed to mix arterial blood from oxygenators with asanguineous cardioplegia solution. The blood/cardioplegia solution is then cooled/warmed and delivered to the patient.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the MYOtherm™ XP Cardioplegia System. The modification to the current MYOtherm™ XP Cardioplegia System is to coat the blood contact surfaces with Carmeda®.

The CBMYOtherm™ XP Cardioplegia System with Carmeda® BioActive Surface is being compared to the following Marketed Devices:

- MYOtherm™ XP Cardioplegia System (K971105)
- CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface (K973475)

The CBMYOtherm™ XP Cardioplegia System with Carmeda® BioActive Surface has the same indications statement and intended uses as the:

- MYOtherm™ XP Cardioplegia System (K971105)

The CBMYOtherm™ XP Cardioplegia System with Carmeda® BioActive Surface has "new technological characteristics (e.g., materials and manufacturing processes)" from the MYOtherm™ Cardioplegia System. The new technological characteristic is solely the coating material of the blood pathway:

- Carmeda®

The technological characteristic of the Carmeda® BioActive Surface is common to other cardioplegia delivery systems currently in commercial distribution as follows:

- CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface (K973475)

This technological characteristic "could affect the safety and effectiveness of the device". However, these "new technological characteristics do not raise new types of safety or effectiveness questions". In addition, "there are acceptable scientific methods which exist for assessing effects of these new technological characteristics".

"Performance data to assess the effects of these new technological characteristics" has been performed. These "performance data demonstrate" that the CBMYOtherm™ XP

Cardioplegia System with Carmeda® BioActive Surface is substantially equivalent to other marketed cardioplegia delivery systems.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the CBMYOtherm™ XP Cardioplegia System with Carmeda® BioActive Surface does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed cardioplegia delivery system. The *in vitro* bench testing included analysis of:

Coating Characteristics

- Coating
- Leaching
- Bioactivity

Physical Characteristics

- Pressure integrity
- Priming volume

Performance Characteristics

- Ease of prime
- Heat exchanger performance
- Pressure drop
- Blood trauma

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Medronic Perfusion Systems
c/o Ms. Marie Holm
Associate Product Regulations Manager
7611 Northland Drive N.
Minneapolis, MN 55428

Re: K003724
Trade Name: MYOtherm™XP Cardioplegia Deliver System with Carmeda® BioActive Surface
Regulatory Class: II (two)
Product Code: DTR
Dated: December 12, 2000
Received: December 13, 2000

Dear Ms. Holm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number if known: K003724

Device Name: CBMYOtherm™ XP Cardioplegia Delivery System with Carmeda® BioActive Surface

Indications for Use:

The CBMYOtherm™ XP Cardioplegia Delivery System with Carmeda® BioActive Surface is a device intended for the mixing, warming/cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio.

Concurrence of **CDRH**, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003724

Prescription Use X
(Per 21 CFR 801.109)

OR

~~Over-The-Counter use~~ ____